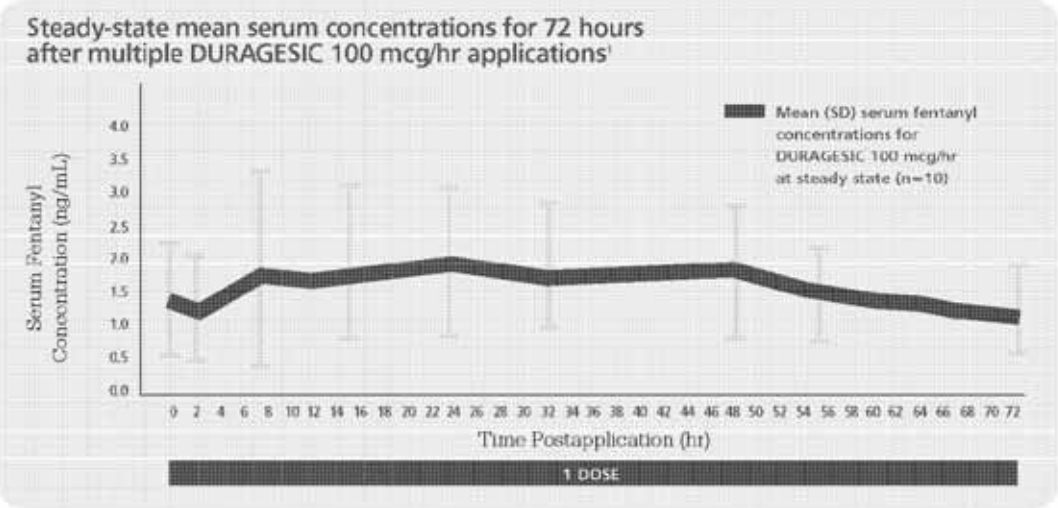
PSJ2 Exh 35

“Now I have the freedom to worry less about my chronic pain”

Chronic pain relief with important patient benefits

Up to 72 hours of uninterrupted pain relief per patch

- Provides fewer peaks and troughs
- Consistent drug delivery over 3 days



As with other drug-level measurements, serum fentanyl concentrations may be useful clinically, although they do not reflect patient sensitivity to fentanyl and should not be used by physicians as a sole indicator of effectiveness or toxicity.

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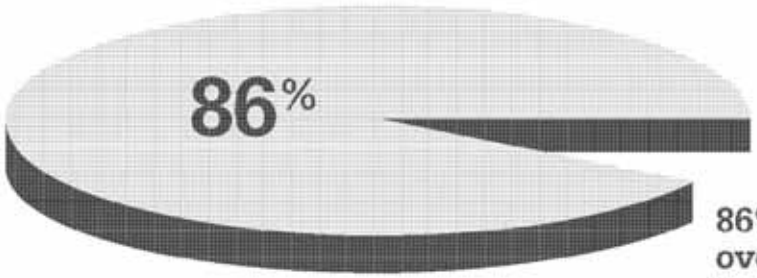
Demonstrated effectiveness in chronic back pain with additional patient benefits



86% of patients experienced overall benefit in a clinical study* based on[2]:

- Pain control
- Disability in ADLs
- Quality of sleep

All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.[1]

Significantly reduced nighttime awakenings.[2]

Significant improvement in disability as measured by the Oswestry Disability Questionnaire and Pain Disability Index.[2]

*Study participants had chronic low back pain inadequately controlled by short-acting opioids. Participants underwent a 9- to 12-day titration phase with transdermal fentanyl; once titration was completed, patients were maintained on transdermal fentanyl for 1 month. Sixty-eight patients were originally enrolled in this study. A total of 18 patients left the study due to nausea and vomiting (10 patients), transportation hardships (4 patients), noncompliance with study protocol (3 patients), and drowsiness (1 patient). No significant change in quality of sleep was observed based on the summed analog VSH Scale.

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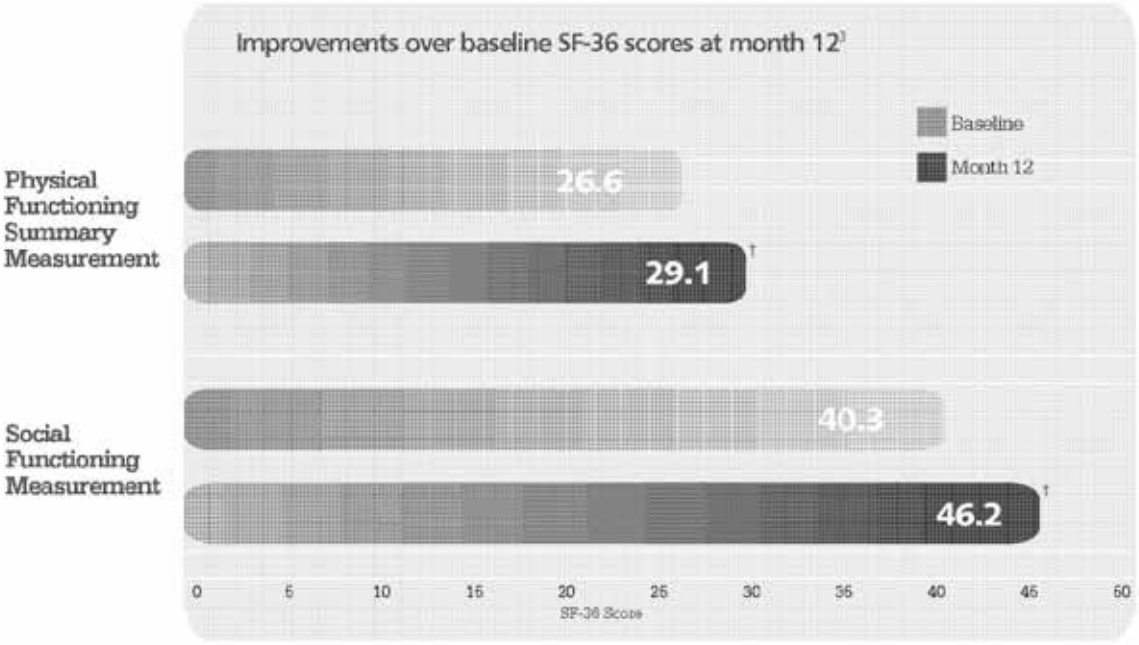
Improvements in physical and social functioning

Results from a long-term study

In a 12-month open-label study, DURAGESIC significantly improved scores for physical functioning summary measurement and social functioning at 12 months ($p<0.05$).*[3]



DURAGESIC also significantly improved scores for bodily pain at 12 months ($p<0.05$).[3]

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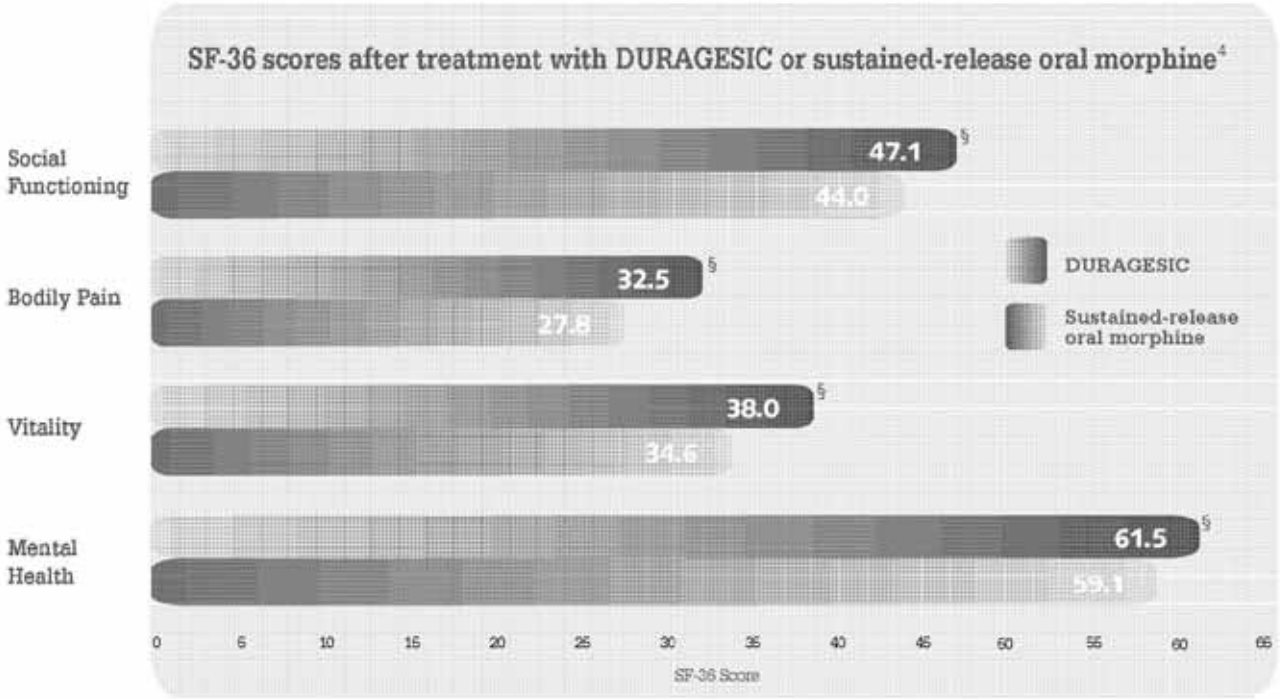
*Study involved 532 patients who had chronic nonmalignant pain for at least 6 weeks preceding the trial that required continuous treatment with a potent opioid; patients must have achieved moderate pain control with a stable daily dose for at least 1 week preceding the trial. Patients received appropriate doses of DURAGESIC for up to 12 months. Mental health summary score was not significant at 12 months. Some SF-36 parameters showed only minor differences between endpoint and baseline analysis. Twenty-five percent of patients discontinued due to adverse events, including nausea (7%), vomiting (5%), somnolence (4%), dizziness (2%), increased sweating (2%), and anorexia (2%). There were 9 deaths during the trial; only one was possibly related to therapy (severe bronchopneumonia).

†$p<0.05$.

Results from a crossover comparison

In an open-label crossover comparison with sustained-release oral morphine, patients using DURAGESIC had significantly higher scores in social functioning, bodily pain, vitality, and mental health ($p<0.05$).[1,4]



Patients using DURAGESIC also had significantly higher physical functioning summary measurement and mental health summary measurement scores ($p<0.05$).[4]

[1]Study involved 256 patients who had chronic nonmalignant pain requiring potent opioids for 6 weeks preceding trial; patients must have achieved moderate pain control with a stable dose of oral opioid for 7 days preceding the trial. Patients were given appropriate doses of DURAGESIC or sustained-release morphine over 4 weeks, followed by a crossover period in which patients were given the equivalent dose of the other therapy for 4 weeks. Within the total patient population, 11% of patients using DURAGESIC and 4% of patients using sustained-release oral morphine withdrew due to adverse events. Among patients who were fentanyl- and morphine-naïve, 11% using DURAGESIC and 9.8% using sustained-release oral morphine withdrew due to adverse events.

[§]$p<0.05$.

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Indication

DURAGESIC® (fentanyl transdermal system) CII is indicated for patients in chronic pain who require continuous opioid analgesia and whose pain cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics, or p.r.n. dosing with short-acting opioids.

BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC IS CONTRAINDICATED:

- In the management of acute or postoperative pain, including use in outpatient surgeries
- In the management of mild or intermittent pain responsive to p.r.n. or non-opioid therapy
- In dosages exceeding 25 mcg/hr at the initiation of opioid therapy

(See CONTRAINDICATIONS section of full Prescribing Information for further information.)

DURAGESIC SHOULD NOT BE ADMINISTERED TO CHILDREN UNDER 12 YEARS OF AGE OR PATIENTS UNDER 18 YEARS OF AGE WHO WEIGH LESS THAN 50 KG (110 LBS) EXCEPT IN AN AUTHORIZED INVESTIGATIONAL RESEARCH SETTING. (SEE PRECAUTIONS—PEDIATRIC USE SECTION OF FULL PRESCRIBING INFORMATION FOR FURTHER INFORMATION.)

DURAGESIC is indicated for treatment of chronic pain (such as that of malignancy) that:

- Cannot be managed by lesser means such as acetaminophen-opioid combinations, nonsteroidal analgesics, or p.r.n. dosing with short-acting opioids and
- Requires continuous opioid administration

The 50, 75, and 100 mcg/hr dosages should ONLY be used in patients already on and tolerant to opioid therapy.

Please see full Prescribing Information, including Boxed Warning.

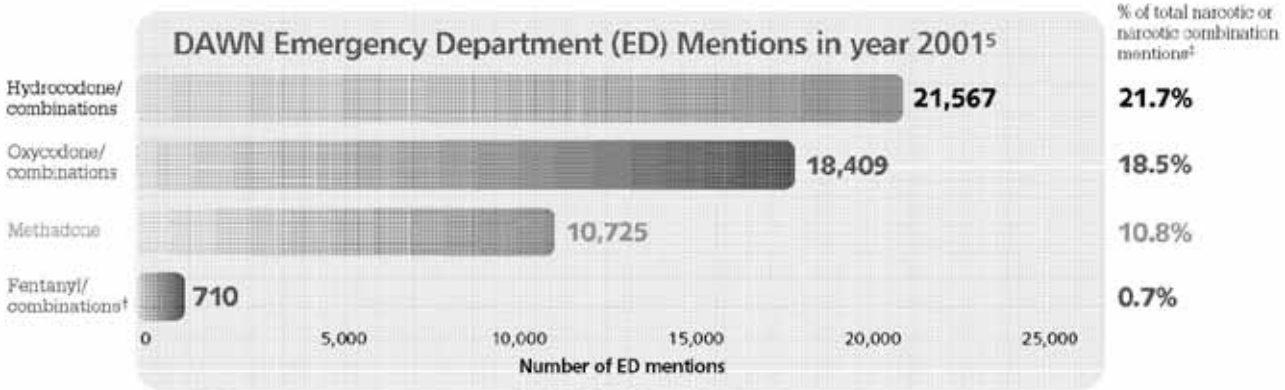
NOTE: Since elderly, cachectic, or debilitated patients may have altered pharmacokinetics due to poor fat stores, muscle wasting, or altered clearance, they should not be started on DURAGESIC doses higher than 25 mcg/hr unless they are taking more than 135 mg/day of oral morphine or equivalent dose of another opioid.

References: 1. Southam MA. Transdermal fentanyl therapy: system design, pharmacokinetics and efficacy. *Anticancer Drugs*. 1995;6(suppl 3):29–34. **2.** Simpson RK Jr, Edmondson EA, Constant CF, Collier C. Transdermal fentanyl as treatment for chronic low back pain. *J Pain Symptom Manage*. 1997;14:218–224. **3.** Milligan K, Lanteri-Minet M, Borchert K, et al. Evaluation of long-term efficacy and safety of transdermal fentanyl in the treatment of chronic noncancer pain. *J Pain*. 2001;2:197–204. **4.** Allan L, Hays H, Jensen N-H, et al. Randomised crossover trial of transdermal fentanyl and sustained release oral morphine for treating chronic non-cancer pain. *BMJ*. 2001. 322:1154–1158. **5.** Department of Health and Human Services. Office of Applied Studies. Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network. *Emergency Department Trends from the Drug Abuse Warning Network, Final Estimates, 1994–2001*. Table 2.8.0; ED mentions for central nervous system agents by drug category: Estimates for the coterminous U.S. by year.

Over a decade of proven clinical experience

Low reported rate of mentions in DAWN data*

Source: Drug Abuse Warning Network (DAWN) database



*Record of data on emergency department (ED) episodes induced by or related to substance abuse.

- Data do not distinguish between IV, transdermal, transmucosal, or illicit fentanyl analogs
- DAWN only captures drug abuse events that result in ED admission
- No data on severity of adverse events or hospital admissions

Favorable side effect profile

Adverse experiences in patients with cancer (N=153)[§]

Adverse experience	Incidence	Discontinued
Nausea	23%	6%
Vomiting	22%	3%
Somnolence	17%	2%
Constipation	**14%**	**0%**
Diaphoresis	14%	0%

Many patients were receiving other regimens, including chemotherapy and radiation.

Minimizes the potential for local GI side effects by avoiding GI absorption.

†Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine. DURAGESIC therefore has the potential for abuse. Tolerance, physical and psychological dependence may develop upon repeated administration of opioids. Iatrogenic addiction following opioid administration is relatively rare. Physicians should not let concerns of physical dependence deter them from using adequate amounts of opioids in the management of severe pain when such use is indicated.

‡A total of 99,317 ED mentions were recorded.

§Please see full Prescribing Information for a more complete list of adverse events.

Give your patients the freedom of a life uninterrupted by chronic pain

- Uninterrupted pain relief for up to 72 hours with fewer peaks and troughs
- Helps patients think less about their pain
- Improvements in physical and social functioning

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Life, uninterrupted.

For more information about DURAGESIC, call Janssen Medical Services at 1-800-JANSSEN (1-800-526-7736) 9 AM to 5 PM, Eastern Time, Monday through Friday.

For additional physician and patient information about the use of DURAGESIC in chronic pain, please visit:

www.duragesic.com

FOR SALES REPRESENTATIVE USE ONLY. Not to be left with physician. Furnish physician with full Prescribing Information, including Boxed Warning.

Together Rx

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